An Implantable FM Telemetry System for Measuring Forces on Prosthetic Hip Joints

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Abstract — This paper is concerned with a totally implantable single channel FM telemetry system that has been designed to operate with a strain gauged version of an English low friction low offset style prosthetic hip joint. This enables measurements of the compressive forces acting on the prosthesis to be carried out via the telemetry system *in vivo*. The need for further investigations into the forces exerted on hip prostheses arose during the development of the English implant, after fatigue and fracture observations had been prevalent in other types of implant.

The paper describes the mechanical and electronic constraints imposed at the design stage of the system, and the final solution adopted. In essence, the system at present consists of a bridged gauge mounted on a carrier inside the prosthesis, which drives a miniature FM transmitter. The FM signal is received, demodulated, processed and displayed on a U.V. recorder in such a way that a direct print out of load patterns during selected activities is obtained. The system has been successfully implanted and operated, and many novel results have been obtained.

In addition to the system description the paper discusses the accuracy of the present system; also ways of improving this accuracy by means of further signal processing, and/or changes in the modulation scheme are outlined.

INTRODUCTION

The need for further investigations into the forces exerted on hip prostheses arose during the development of the English implant (English, 1975), after fatigue and fracture observations had been prevalent in other types of implant. Extensive mechanical testing of the implant had been carried out, but actual data on prosthetic hip forces was not available. Indeed, the published literature for walking forces in the femur varied from 1.8 to 7 times body weight, thereby making meaningful fatigue testing of the implant impossible. Most of the previous work on force measurement had been based on 'indirect' calculations, the only *in vivo* study being that of

Rydell, 1966. This study was limited in that measurements were started 6 months after operation, and restricted to one week because of the need to bring signal wires out through the skin.

It was therefore decided to measure directly the forces acting on the head of an English hip prosthesis using strain gauges, and to transmit this information out of the body via an implanted radio transmitter. The system has been designed and implanted, and the results obtained are the first ever reported results of *in vivo* measurement of human hip loads using a telemetric output.

DESIGN CONSTRAINTS

Several constraints have been elemental in producing the final system design. These are as follows:

(a) The hip prosthesis should be an English model C and the strain gauges should be mounted on the implant. These gauges will therefore be physically small, and give a low output.
(b) The transmission system should be totally implantable. The transmitter module must therefore be physically removed from the implant and strain gauges.
(c) Measurements should be made over as long a period of the patient's recovery as possible. Thus the transmitter requires high capacity batteries, and some means of switching them on and off externally, in order to conserve power.
(d) The transmitter must be physically small enough to be easily buried in body fat.
(e) Forces in the range $0 \rightarrow 9000$N, with a resolution of ≈ 50N are to be measured.

TRANSMITTER DESIGN

STRAIN GAUGES

The main factor governing the type of transmission scheme used is the type of strain gauge employed. The English prosthesis is manufactured in 316 stainless steel which yields at a strain level of approximately 0.04 percent. At a force of 2224N the strain expected is 0.0112 percent. This means that the maximum possible change in gauge resistance ΔR, relative to original resistance R, is given by:

$$\frac{\Delta R}{R} = eK \tag{1}$$

where e is the strain and K is the 'gauge' or K factor of the gauge which lies between 2 and 6 for metal gauges. Thus, for example, with a high output platinum-tungsten gauge which has $K = 4.5$, the maximum ratio $\Delta R/R$ is ≈ 0.2 percent. In addition, this value is the maximum $\Delta R/R$, and in normal operation the loads expected would cause a change in resistance considerably less than this (say 100 times less). It is therefore necessary to operate several strain gauges in a bridge arrangement in order to produce a suitable output signal.

Figure 1 illustrates the solution adopted and shows the prosthesis which is different from the normal clinical model in that it is manufactured in two parts. The head part which forms a removable piston and fits into a cylinder machined out of the specially thickened neck of the femoral component. The removable neck is machined to allow for four miniature Dentronic 1800 series platinum tungsten strain gauges ($R = 350\ \Omega$) to be mounted around its circumference thus forming a simple load cell. Figure 2 shows a typical strain gauge, and Fig. 3 shows the bridge arrangement used for the gauges. The gauges are placed 90° apart around the circumference of the load cell. Each one has its gauge length axis at right angles to its neighbor. In axial

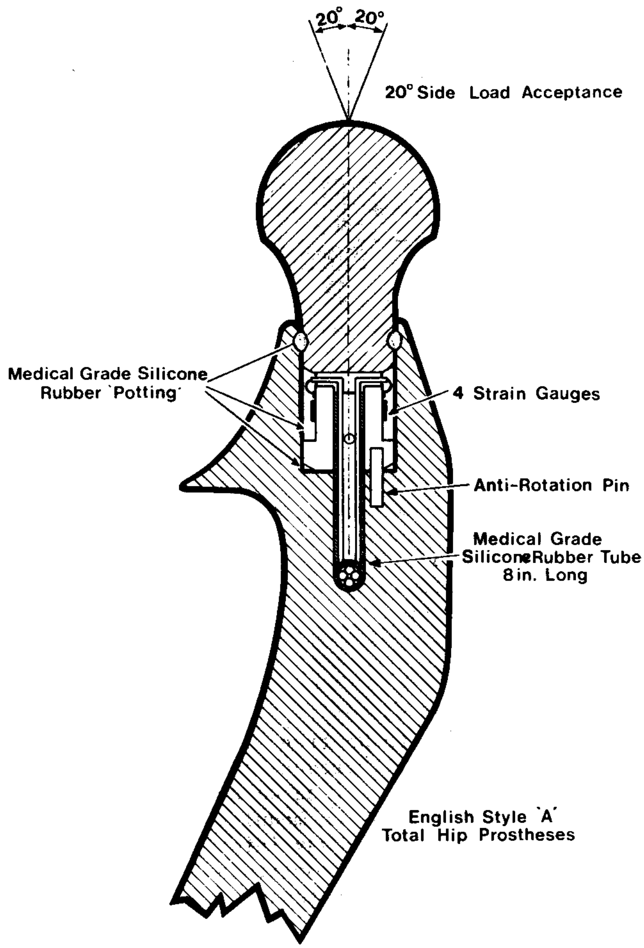

Fig. 1. English hip prosthesis.

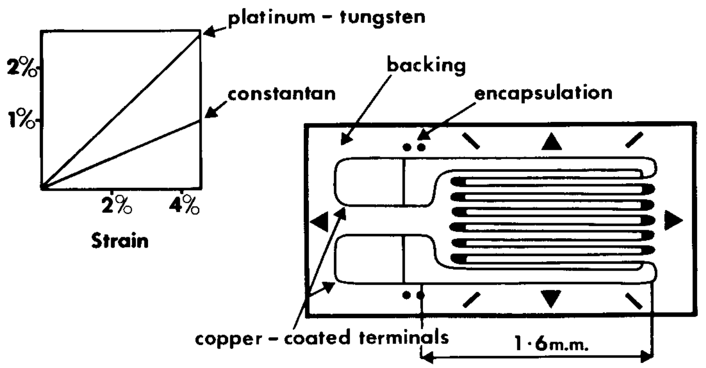

Fig. 2. Implant strain gauges.

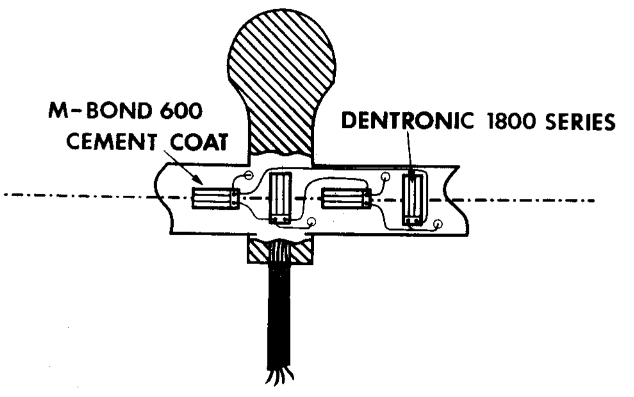

Fig. 3. Implant inter gauge wiring.

compression all four gauges detect strain, although the two having their gauge length axis aligned around the circumference do to a lesser extent. These circumferential gauges also ensure that the unwanted effect on the bridge of front/back off axis loading is minimized. No temperature compensation is included in the bridge for reasons of simplicity, and because the body should remain at sufficiently constant temperature to make compensation unnecessary for reasons of accuracy.

MODULATION SCHEME

In this application the information to be transmitted is essentially dynamic d.c., that is, loading of the prosthesis will produce a certain d.c. output from the gauge bridge. Following normal telemetric practice we should therefore use the bridge output to drive some form of pulse duration modulator, whose output pulse train can then modulate an FM transmitter. In this way information is in the mark/space ratio of the pulse train, and is independent of amplitude levels and hence battery life. This solution was not adopted for several reasons. The bridge output from no load to maximum is only about 0 to 3 mV V^{-1} input. In order to drive a pulse duration modulator this signal would have to be amplified, thus requiring more transmitter circuitry and giving lower battery life. Alternatively a high bridge input voltage would have to be used, and this would require a physically larger transmitter.

The final solution was to adopt a simple amplitude modulation system, and to check that accuracy was maintained over a reasonable proportion of the battery life by extensive pre-implantation testing.

TRANSMITTER SYSTEM

Figure 4 shows the final transmitter circuit design. The LM3909 oscillator chip runs off a single 1.35 V battery (Duracell mercury WH 3T2, 220 mA h) and produces a 1 V amplitude 1 KHz square wave which is used to excite the strain gauge bridge. The output of the bridge is balanced to about 0.5 mV peak-to-peak by means of the parallel balance resistor. The bridge output is approximately 3 mV at full load (9000N), and is very noisy due to the inherent chip noise in the excitation signal.

The bridge output is used to modulate directly an FM transmitter chip (SN102F) which operates on the VHF biotelemetry band at 102.3 MHz. The maximum input amplitude is 4 mV, so that bridge and transmitter are well matched.

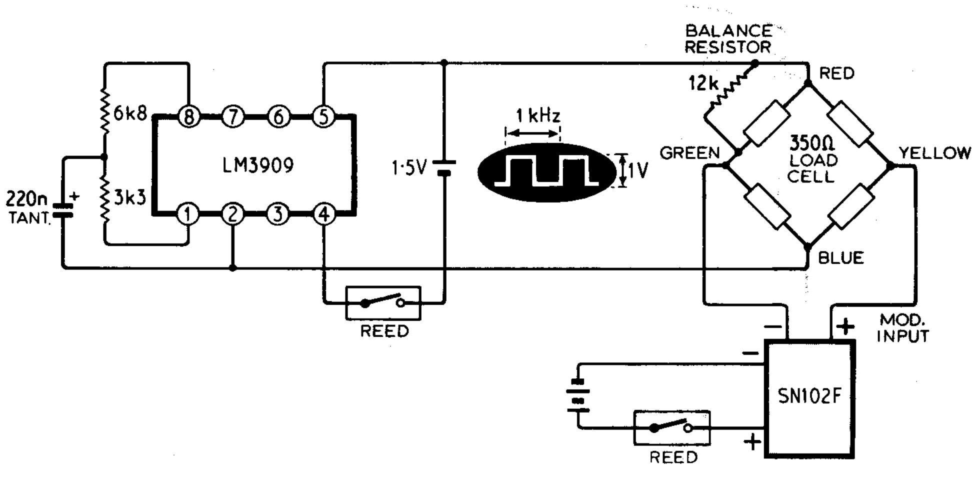

Fig. 4. Transmitter circuit.

Both the oscillator (1.5 V) and transmitter (2 × 1.35 V) battery circuits are fitted with subminiature reed switches which enable power to be switched on and off via a magnet at distances of between 25 to 50 mm from the transmitter. Battery life is approximately 70 h.

Figure 5 shows the mechanical construction of the transmitter which is approximately 25 × 35 × 10 mm and Fig. 6 shows the implanted system. Encapsulation is of paramount importance in any human implant and the required medical standard is achieved as follows. The gauges are sealed from the body fluids by coating with type A silicone adhesive. The cavity is allowed to cure and is applied slightly proud of the piston diameter. A further seal is provided by the addition of a groove in the neck and piston components, which are machined to line up on assembly. These grooves are filled with medical grade silicone rubber and allowed to cure, again slightly proud of the piston diameter. The polyvinyl chloride (PVC) wires attached to the strain gauges are covered by a thin walled silicone rubber sleeve which is sealed into the piston center hole with silicone adhesive. The cable is passed through the implant stem with the silicone sleeve protruding about ½ in. The main length of the PVC wires is then coated with Silastic adhesive type 'A' and a thick walled silicone rubber tube passed over them to bolt up to the implant stem and over the short length of thin walled tube. The signal cable is then attached to the transmitter and the Perspex box is filled with epoxy resin. The whole unit and cable are then covered in a moulded Silastic (382) covering.

THE RECEIVING SYSTEM

Figure 7 shows the receiving system. The FM signal from the transmitter is received on a simple 3 in loop antenna taped to the patient's skin. The antenna cable is long enough to allow complete freedom of movement when the patient is undergoing tests. The antenna signal is received and demodulated using standard Mullard modules. The noisy square wave receiver output is then passed to the main filtering circuits and to an audio amplifier/loudspeaker system. The signal is processed in the following way to provide a noise free d.c. signal whose amplitude varies in sympathy with the amplitude of the receiver output square wave. This d.c. signal is required to drive the chart recorder.

The noisy square wave is first passed through a 1 KHz Q = 10 bandpass active filter

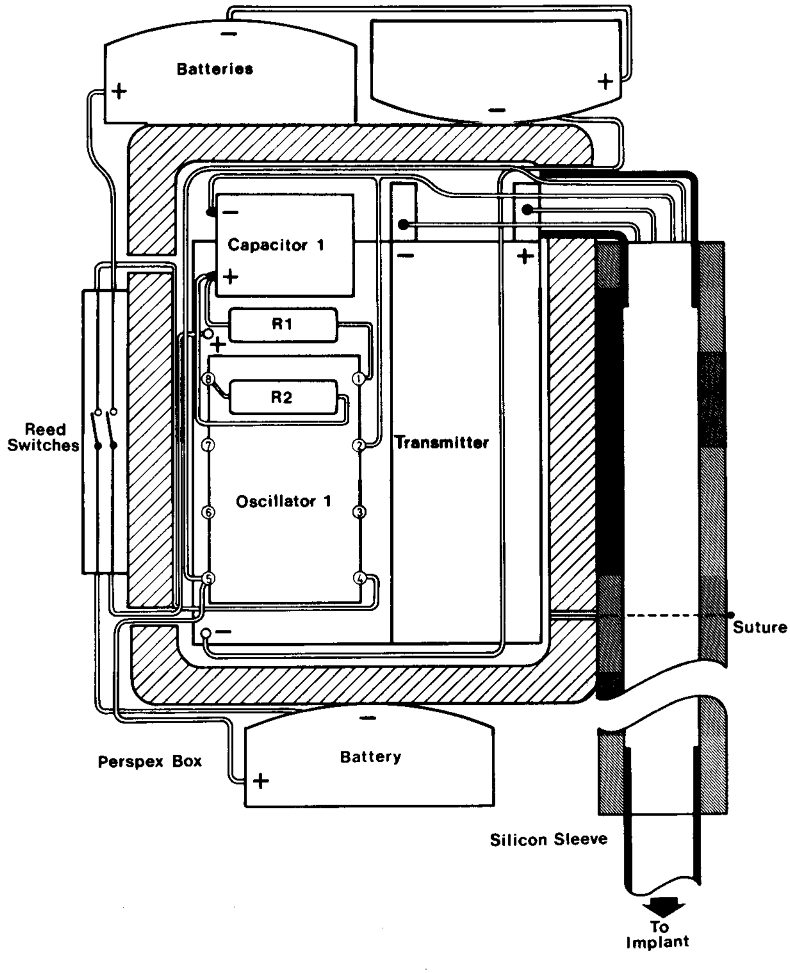

Fig. 5. Transmitter construction.

to remove all high frequency noise. The resulting 1 KHz output is buffered and fed to a precision full wave rectifier. The rectifier output is therefore a d.c. signal with a large amount of 2 KHz ripple. This signal is sufficient to drive the tuning meter. The signal is then smoothed by the integrating action of the 15 Hz low pass filter. The output is now d.c. with low ripple. The next stage performs level shifting and attenuation to provide a signal suitable for driving the U.V. recorder.

CALIBRATION AND ACCURACY

The implant and telemetry system were extensively calibrated and tested before implantation. A modified fatigue testing machine was used for calibration. The machine was capable of applying known static or dynamic loads of up to 9000N. Four ranges of load were recorded using a force applied axially down the implant head and neck. The ranges were: 0-2224N, 0-4448N, 0-6672N, 0-8896N. In addition, loads were applied at 20° angles to the axis within the range 0-4448N. This 20° off axis loading was felt to be the greatest direction at which a force would be applied to the implant head during normal walking or high load activities, and gave rise to an apparent fall in force of 7 percent when compared with axial loading.

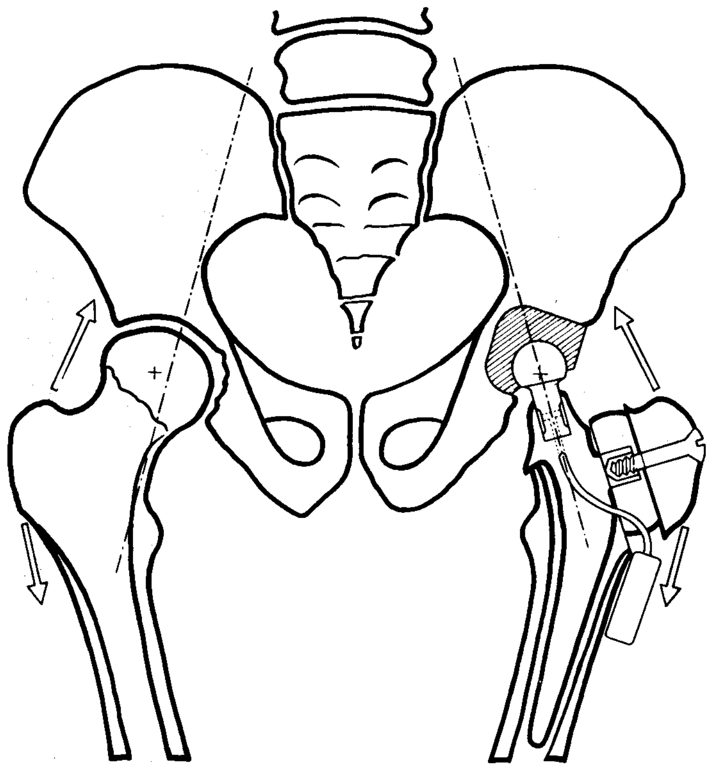

Fig. 6. Implanted system.

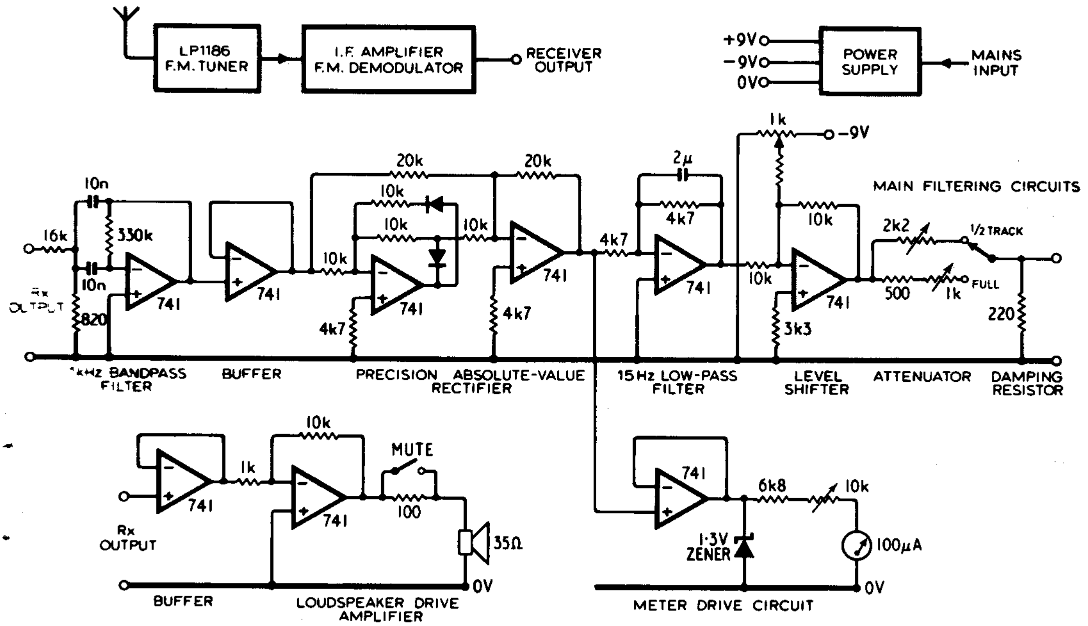

Fig. 7. Receiver circuits.

The system accuracy is affected by several factors. Firstly, the strain gauges are not temperature compensated, and the transmitter frequency varies with temperature. Secondly, because of the amplitude system used, receiver tuning (and hence transmitter temperature) affects the output U.V. recorder signal. Thirdly, off axis forces cause an apparent reduction in load. Fourthly, metal deformation and gauge 'creep' will affect results in high force activities such as running.

However, the system gave dependable and repeatable results when tested at body temperature, over several months, and over the period of transmitter battery life. An overall resolution of 40N in the range 0-2224N was obtained, and the overall system accuracy is estimated at ± 10 percent.

RESULTS

The patient selected for the operation was female and weighed 79.8 kg. The system provided hip force records at the implantation operation and at regular intervals during a 40 day period. Because of the factors mentioned above it was important to obtain an accurate base line recording for the zero force level at operation time. Figure 8 shows the recorded signal (in terms of patient body weight) at various times during the operation. The zero level was obtained by allowing the implant and transmitter to stabilize to body temperature but with the hip still dislocated.

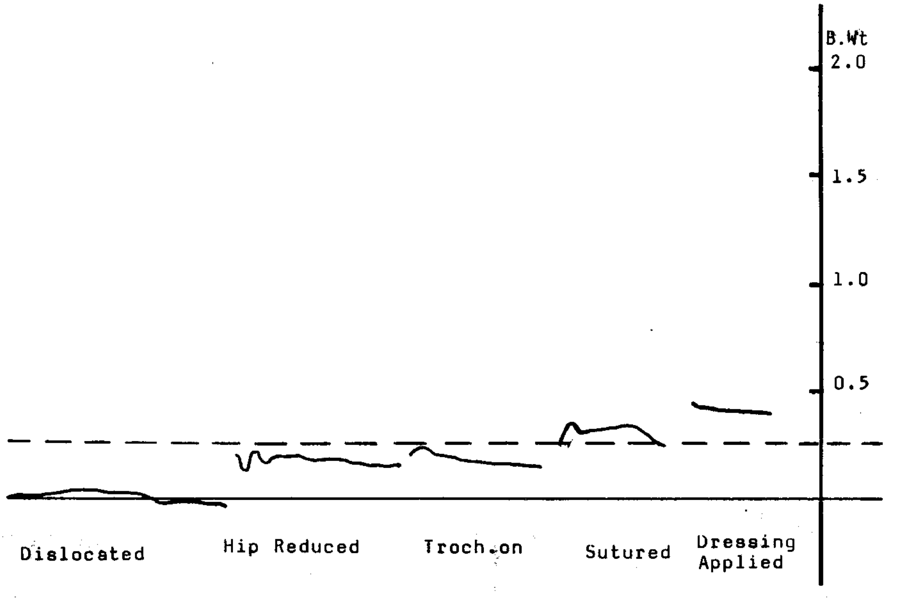

Fig. 8. Recorded hip load (AW). Day 0 — signal height at operation.

Subsequent results were taken with the patient supine, standing, walking with and without sticks, and stair climbing. Figure 9, for example, shows walking results on day 12.

CONCLUSIONS AND DISCUSSION

After day 40 no further signals were received. A possible cause of failure could have been the choice of silicone rubber for encapsulating the strain gauges as it

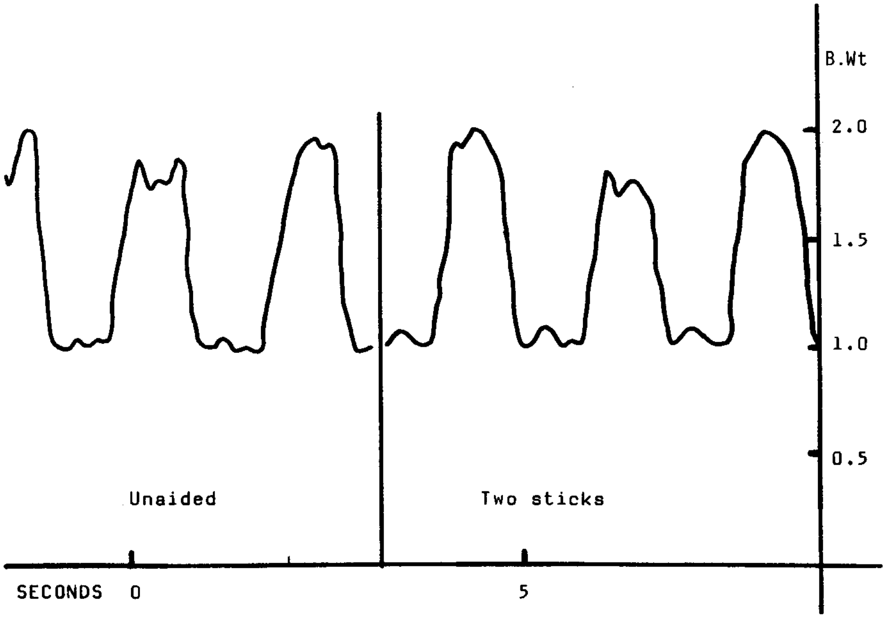

Fig. 9. Recorded hip loads (AW). Day 12 — walking with and without sticks.

has since come to our notice that the acetic acid present in uncured silicone could have corroded the gauges or solder connections.

The records obtained have given valuable information regarding forces acting on the head of the type of implant used. The design of the implant was intended to reduce bending loads on the stem and the operative technique (English, 1975) was intended to reduce the overall force acting across the hip joint by offsetting the trochanter and displacing the center for rotation towards the midline. The risk of dislocation, fatigue failure, and loosening is lower using this technique than with more standard implants.

The results obtained can be summarized as follows. Stance phase force, and swing phase force, were found to be 2.0 times and 1.0 times body weight respectively. The one-legged stance caused forces of 2.54 times and 2.18 times body weight at 12 and 40 days after operation.

The telemetry system has operated satisfactorily and given useful results. It is, however, possible to improve the system, and this is under consideration for any future clinical trials. Firstly, we can consider improvements to the existing design. These could take the form of temperature compensation on the strain gauges, and automatic receiver tuning via feedback from the filtered 1 KHz signal. This would alleviate transmitter temperature effects considerably, and speed up the determination of zero force at operation time. Secondly, we can consider redesigning the system to operate with a pulse duration modulation scheme. This would require a more complex transmitter, but in conjunction with strain gauge temperature compensation, would provide an absolute zero force level, in which system accuracy would be almost completely independent of transmitter temperature, amplitude, and frequency drifts. One possible way of achieving this is to consider the use of semiconductor strain gauges which have K values of up to 200. Such gauges, however, are extremely temperature dependent and would require complex compensation circuitry to be effective.

Finally, we can assert that the system has established the forces acting on this style of hip prostheses to within ± 10 percent, and that future clinical tests with improved electronics and gauge protection will be directed to confirming these results at greater accuracy, over longer periods of time, and with more varied activities.

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